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CERT038PUS

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Cervical intervertebral prosthesis

Cervical intervertebral prostheses are known (EP-A-1 344 508) having two cover plates which are to be
5 connected to the end plates of the adjacent vertebral
bodies and between which there is a sliding core which
allows the cover plates a relative movement intended to
simulate the articulated mobility of the intervertebral
10 disk that has been replaced. To secure the cover plates
in their intended position between the vertebral
bodies, the cover plates in the known prosthesis are
connected to securing plates which extend from the
ventral edge of the cover plates, perpendicularly
thereto, and are screwed to the ventral surface of the
15 associated vertebral body. The ventral surfaces of the
vertebral bodies on which the securing plates come to
lie do not always extend exactly perpendicular with
respect to the end plates of the vertebral bodies on
which the main surfaces of the cover plates come to
20 lie. This prevents the securing plates from bearing
across their entire surface on the vertebral bodies,
and it impairs the stability of the cover plates.

This shortcoming is remedied by the features of the
25 invention as set out in Claim 1. According to this, the
securing plate is a separate part which is unconnected
to the cover plate. Consequently, the securing plate,
independently of the position of the cover plate, can
assume the attitude corresponding to the position and
30 shape of the ventral surface of the vertebral body. In
this way, an optimal fastening of the securing plate on
the vertebral body is possible. It protrudes with a
limit stop part in front of the intervertebral space
and thereby ensures that the associated cover plate
35 cannot escape in the ventral direction. Therefore, the
securing function of the securing plate is not impaired
by the fact that it is separate from the cover plate.

However, it is unable to prevent the cover plate from shifting in the dorsal direction. The invention is therefore preferably intended for those cover plates which are equipped with suitable means for preventing this dorsal movement. Cover plates provided with a dorsally facing limit stop surface (WO-A-03 075 804) are therefore especially suitable.

An important advantage of the invention is that it allows the cover plate to be used with or without securing plate. For this, it was hitherto necessary to keep different cover plates in stock, namely those with and those without securing plate.

A further advantage of the invention is that micro movements of the cover plate, which may occur as a result of normal neck movement, are not transmitted to the securing plate and, therefore, cannot lead to loosening of its fastening means. Nevertheless, it may be expedient to equip the fastening screws with a device securing them against inadvertent loosening.

In connection with one prosthesis, it is possible to use two securing plates which are fastened, lying opposite one another, on the adjacent vertebral bodies, in order to secure one or other cover plate of the prosthesis. In general, however, it suffices to secure one cover plate with a securing plate in order to effectively prevent all parts of the prosthesis from escaping in the ventral direction from the intervertebral space.

It will be appreciated that the securing plate should have a predetermined position in relation to the cover plate. It should in fact extend sufficiently over the vertebral body and in front of the intervertebral space in order to be able to accomplish the securing function. On the other hand, it should not protrude too far, so as not to impede the relative movement of the

vertebral bodies or of the prosthesis parts with respect to one another during the articulation movement. In order to position the securing plate, it is therefore expedient to use an instrument designed as
5 a drill gauge for the fastening screws of the securing plate. This drill gauge can be provided with means giving it a predetermined position in relation to the implanted prosthesis. Instead of this, it can also interact with, or be fixedly connected to, a prosthesis
10 model which is fitted into the intervertebral space prior to implantation of the prosthesis.

According to a special feature of the invention, the securing plate can be biodegradable. For this purpose,
15 the material is chosen and dimensioned in such a way that it remains in situ and can perform its securing function at least for the period of time until the associated cover plate of the prosthesis has connected definitively to the adjoining bone tissue. As soon as
20 this is the case, i.e. when the bone tissue has connected to the surface of the cover plate so intimately that a relative displacement is no longer possible under the forces that apply, the securing plate is no longer necessary. The time required for
25 this to happen is of the order of several months, for example two to six months.

The invention is explained in more detail below with reference to the drawings which depict an advantageous
30 illustrative embodiment, and in which:

Fig. 1 shows a sagittal section through the prosthesis in the implanted state,

35 Fig. 2 shows a side view of the prosthesis without securing plate, and

Fig. 3 shows a drill gauge for the fastening screws of the securing plate.

Between the vertebrae 1 and 2 of the cervical spine there is an intervertebral space into which is inserted the intervertebral prosthesis consisting of an upper
5 cover plate 3, a lower cover plate 4, and a prosthesis core 5. The prosthesis core 5 is held on the lower cover plate 4 by profiles 6 and a catch 7. With the upper cover plate 3, it forms a slide surface pairing 8. The cover plates 3 and 4 have a sawtooth formation 9
10 by means of which they are held on the associated end plates of the vertebral bodies 1, 2. Short flanges 10 with dorsally facing limit stop surfaces 11 ensure that the cover plates 3, 4 cannot move farther than is wanted in the dorsal direction relative to the
15 vertebral bodies 1, 2. An undesired movement in the ventral direction is generally prevented by the sawtooth formation of the profiles 9. This at least applies several months after the operation, when the bone tissue has grown into the surface of the cover
20 plates and has connected firmly to them. Details of this construction are described in the publication WO 03/075804 A1.

There are cases where, because of special physiological
25 circumstances, a risk of ventral displacement of the prosthesis must be taken into account. This risk may also arise for a period until the abovementioned connection between the cover plates and the bone tissue is secure. In these cases, the cover plate in question
30 is combined with a securing plate 12 which, in the example in Figure 1, is attached to the ventral surface of the caudal vertebral body 2 by means of screws 13. A part of the securing plate 12 designated as limit stop part 14 extends above the vertebral body 2 in such a
35 way that it lies in front of part of the associated prosthesis cover plate 4. If the latter has a tendency to move out of the intervertebral space in the ventral direction, it will strike against the limit stop part 14 of the securing plate 12 and thus be prevented from

moving any farther in this direction.

The securing plate 12 is shown on the caudal vertebral body 2. However, a securing plate could be attached, in addition or instead, to the cranial vertebral body 1.

The way in which the securing plate is attached is not important as regards the invention. The most obvious way is to use bone screws, expediently provided with a means (not shown) to secure them against loosening. They can be screwed in substantially parallel to the main plane of the prosthesis in the vertebral body. It is particularly advantageous for them to be inclined away from the prosthesis in the dorsal direction, as is depicted.

The securing plate 12 does not have to be positioned with great precision. It suffices if it is placed at a suitable location, preferably over a large part of the width of the prosthesis, and extends into the path which the prosthesis would take in the event of an undesired movement in the ventral direction. For this, it suffices if it extends 1 or 2 mm above the edge of the vertebral body 2. It should not extend any more than about 2.5 to 3 mm above it, so as not to impede the relative flexion movement of the vertebral bodies 1, 2 and of the prosthesis parts.

To make the positioning easier, the securing plate 12 can be provided with an edge 15 which corresponds to the edge, designated by the same reference number, of the vertebral body 2 and separates the limit stop part 14 of the securing plate from that part which is to be fastened to the front surface of the vertebral body. When the limit stop part 14 has the desired height of about 2 mm, the surgeon proceeds by placing the securing plate on the vertebral body 2 in such a way that the edges 15 of the securing plate and vertebral body lie on one another. He then drills the holes for

receiving the fastening screws 13 by using the screw holes 16 in the securing plate as drill gauges. In this way, he achieves a secure positioning.

5 A still more secure positioning is achieved by using the instrument shown in Figure 3. A drill gauge 20 with bore holes 21 for guiding the drill is arranged on a forceps-like instrument having two arms 22, 23 which, by means not shown, can be moved toward one another in
10 the direction of arrow 24 and can be fixed in the approximated position. On their flanks facing one another, the arms 22, 23 have projections 24, 25 which are of a configuration that matches the corresponding recesses 26, 27 of the prosthesis, and, in the example
15 shown, these projections are specifically pins 24, which correspond with bores 26, and blades 25 which correspond with slits 27. After the prosthesis 3, 4, 5 has been inserted into the intervertebral space, as is shown in Figure 1, the instrument is applied to the
20 prosthesis and adjusted thereon with the aid of the elements 24 to 27. The bores 21 of the drill gauge 20 are now located on the same axis in a position in which the bores are intended to be provided for the fastening screws 13 of the securing plate.

25 The instrument shown in Figure 3 is especially suitable for a securing plate to be arranged in the caudal direction from the prosthesis. This is due to the arrangement of the elements 24 to 27. To prepare for a
30 securing plate which is to be fastened in the cranial direction, it can also be equipped with a corresponding drill gauge on its top face as viewed in Figure 3.

35 Seen from the ventral direction, the securing plate shown in Fig. 1 can be made slightly rectangular or oval with a greater dimension in the lateral direction than in the caudal-cranial direction. In a particularly advantageous embodiment, it is designed as a circular disk, like a clothes button, with a screw hole at its

center. The advantage of this embodiment is that, during the operation, attention need be paid only to a correct positioning of the fastening screw, not to the orientation of the securing plate. The shape of the circular disk also has the advantage that it is less likely to cause irritation of the surrounding organs than is a rectangular plate. This applies especially if the edges, in particular the ventral edges, are rounded.

The securing plate can be made of metal or of a sufficiently resistant plastic. If the cover plate interacting with it is made of metal, a plastic is preferably chosen, or a plastic insert which forms the dorsally oriented surface of the limit stop part 14.

If the securing function of the securing plate is needed only temporarily, for example until the cover plates of the prosthesis have fused sufficiently with the adjoining bone tissue, the securing plate and its fastening means, for example the screw 13, can be made of biodegradable material. Such material is known and, therefore, does not have to be explained here. It is attacked and somehow broken down by the body. The time it takes for this to happen can be influenced by the choice of material. It is chosen such that the securing plate and its fastening means can exert a sufficient securing force for as long as is necessary, for example for a period of four months after the operation.